



May 24, 2021

VIA E-FILING

The Honorable Colm F. Connolly
J. Caleb Boggs Federal Building
844 N. King Street
Room 4124; Unit 31
Wilmington, DE 19801-3555



RE: *Par Pharmaceutical Inc., et al. v. Eagle Pharmaceuticals Inc.*
C.A. No. 18-cv-823-CFC-JLH

Dear Judge Connolly:

We represent the Plaintiffs (collectively “Par”) in the above-captioned Hatch-Waxman Act case, in which defendant Eagle Pharmaceuticals, Inc. (“Eagle”) seeks FDA approval to launch a generic version of plaintiff Par’s Vasostrict® product. The Court has scheduled a joint status call in this matter and *Par v. Amneal* (18-cv-2032) for Wednesday, May 26, 2021, at 9:00 am.

Following the postponement of the trial date in light of Eagle’s late disclosure of important testing data, Plaintiffs conducted discovery of Eagle and its contract manufacturer, AMRI. That discovery is complete, and Par has provided an updated infringement report. Eagle has indicated that it intends to serve a reply report this week.

With respect to the FDA, Eagle’s ANDA has not been approved [REDACTED]
[REDACTED] Eagle has publicly stated that it is doing further testing at the FDA’s request. Assuming the tests are successful, Eagle would then need to make an additional submission to the FDA. The FDA has 6 months to review any new filing on an expedited track or 8 months on the normal track. At that point, the FDA might approve or reject the amended ANDA.

Respectfully submitted,

/s/ Michael J. Farnan

Michael J. Farnan

cc: Counsel of Record (Via E-Mail)